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Inspections, Compliance, Enforcement, and Criminal Investigations

Shemshad Food Products, Inc 3/11/11



Department of Health and Human Services

Public Health Service
Food and Drug Administration
Los Angeles District
Pacific Region
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Telephone: 949-608-2900
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WARNING LETTER

CERTIFIED MAIL RETURN RECEIPT REQUESTED

March 11th, 2011

W/L 28-11

Mr. Cyrus Teadolmanesh, President
Shemshad Food Products, Inc.
3047 Rosslyn St.
Los Angeles, CA, 90065

Dear Mr. Teadolmanesh:

The U.S. Food and Drug Administration (FDA) inspected your manufacturing facility, Shemshad Food Products, Inc, located at 3047 Rosslyn St, Los Angeles, CA, 90065, on September 23-30, 2010. You are manufacturing acidified foods, juices, and other food products. The inspection revealed serious violations of the Acidified Food regulations [21 Code of Federal Regulations (CFR) Parts 108 and 114], the Current Good Manufacturing Practice regulation for food [21 CFR, Part 110], the labeling provisions of Section 403 of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 343], and the provisions of Section 505 of the Act that address the marketing of new drugs [21 U.S.C. § 355].

Based on your failure to comply with 21 CFR Part 114 we have determined that your acidified products including vegetable stew, walnut stew, split pea stew, pickled turnip, pickled garlic, pickled eggplant, pickled asparagus and chopped mixed vegetables packed in glass jars are adulterated within the meaning of Section 402(a)(4) of the Act [21 U.S.C. § 342 (a)(4)] in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health.

As an acidified food processor, you are required to comply with the Act and the federal regulations relating to the processing of acidified foods. These regulations are described in 21 CFR Part 108, Emergency Permit Control, and in 21 CFR Part 114, Acidified Foods. The Emergency Permit Control regulation was issued, in part, pursuant to Section 404 of the Act [21 U.S.C. § 344]. A temporary emergency permit may be required for acidified foods whenever a processor fails to fulfill the mandatory requirements of 21 CFR Part 108, Subpart B, including registration and filing of process information, and the mandatory requirements within 21 CFR Part 114.

Additionally, based on your failure to comply with the requirements of the Current Good Manufacturing Practice (CGMP) regulation in 21 CFR Part 110 we have determined that your food products are adulterated within the meaning of Section 402(a)(4) of the Act, [21 USC § 342(a)(4)] in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health.

Also, as further discussed below, your firm produces a variety of products that are misbranded within the meaning of Section 403 of the Act. Moreover, one of your product is a "new drug" under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C. § 355(a)].

You may find the Act, the Acidified Food regulations, and the CGMP regulations for food through links in FDA's home page at www.fda.gov¹.

The significant violations documented during the inspection include the following:

Acidified Foods

1. You must provide the FDA, before packing any new product, information on the scheduled processes for each acidified food in each container size to comply with 21 CFR 108.25(c)(2). Your firm manufactures acidified foods including but not limited to vegetable stew, walnut stew, split pea stew, hot pepper sauce, fine mixed vegetables, coarse mixed vegetables, pickled garlic and pickled turnip. You have not filed any scheduled processes with the FDA for the acidified foods you manufacture.
2. You must maintain processing and production records showing adherence to the scheduled processes, including records of pH measurements and other critical factors intended to ensure a safe product, to comply with 21 CFR 114.100(b). However, you did not maintain any records of pH measurements or other critical factors for your acidified foods manufactured between November 2008 and August 2010.
3. Each container of acidified foods must be marked with an identifying code specifying, among other things, the year, day, and period during which it was packed, as required by 21 CFR 114.80(b). However, on September 23, 2010, numerous acidified foods including pickled mixed vegetables, walnut stew, vegetable stew, and hot pepper sauce were found stored in your warehouse for distribution that were not marked with an identifying code.
4. You must maintain records identifying initial distribution of the finished product, to comply with 21 CFR 114.100(d). However, our inspection found you do not maintain records identifying initial distribution of finished products.
5. You must prepare and maintain files on a current procedure that includes plans for distributors to follow for recalling products, to comply with 21 CFR 108.25(e). However, our inspection found you do not maintain such a procedure.
6. You must maintain records of examinations of raw materials, packaging materials, and finished products, and of supplier's guarantees or certifications that verify compliance with FDA regulations, to comply with 21 CFR 114.100(a). However, our inspection found you do not maintain such records.
7. Instruments used for measuring pH must be accurate, to comply with 21 CFR 110.40(f). Under 21 CFR 114.90(a)(3)(iii), the accuracy of most pH meters is stated to be approximately 0.1 pH unit, and reproducibility is usually +/-0.05 pH unit or less. However, our inspection found your pH meter was not accurate, because it read 3.68 when tested in a 4.0 buffer. Controlling the pH of acidified foods is essential for product safety and your pH

meter must be accurate to enable you to monitor the process.

Current Good Manufacturing Processes

1. All persons working in direct contact with food, food-contact surfaces, and food-packaging materials must wash their hands thoroughly (and sanitize if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility after each absence from the work station and at any other time their hands may have become soiled or contaminated, to comply with 21 CFR 110.10(b)(3). However, throughout the inspection, employees were observed moving between different rooms, emptying trash, touching the floor, and/or handling other unsanitary objects and then putting on a pair of gloves and starting to work in production without washing or sanitizing their hands. On at least eight occasions, employees were observed leaving their workstation with gloved hands and returning to work in production while wearing the same pair of gloves. On September 27, 2010, an employee was observed leaving his food production workstation, retrieving boxes from the warehouse and then returning to processing ready-to-eat dried fruit snacks without first washing and sanitizing his hands.
2. Hand-washing facilities must be furnished with running water at a suitable temperature, as required by 21 CFR 110.37(e). Our inspection found the hand-washing sink in the processing room lacked hot water.
3. Effective measures must be taken to exclude pests from the processing areas and protect against the contamination of food on the premises by pests, as required by 21 CFR 110.35(c). However, a 55 gallon drum of cooked in-process apples in the processing room contained insect larva and flying insects. Live and dead cockroach-like insects were observed on food processing tables, walls, and on in-process food containers within the processing room, hallways, and office areas. Flying insects were observed in processing rooms and ingredient storage areas.
4. You must identify, hold, and store toxic cleaning compounds and sanitizing agents in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials, to comply with 21 CFR 110.35(b)(2). However, cleaning and sanitizing agents were observed stored among raw ingredients, food utensils, and packaging materials. In addition, at least two of these cleaning and sanitizing agents were stored in unmarked containers.
5. You must locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food, food-packaging materials, and food-contact surfaces, to comply with 110.20(b)(6). However, on September 23, 2010, a dust-covered exhaust fan was observed circulating air inside of the front drying room where racks of uncovered ready-to-eat dried fruit snacks were held to dry. On September 27, 2010, the air vent in the cooking room, which was covered with dust, debris and peeling paint, was observed blowing air directly on uncovered in-process Sour Cherry Juice.
6. Equipment and containers used to convey, hold, or store work-in-process must be constructed, handled, and maintained during manufacturing or storage in a manner that protects against contamination, to comply with 21 CFR 110.80(b)(7). However, our inspection found that you are storing 5 gallon drums of in-process foods including acidified foods and fermenting fruit outside in the parking lot area. Drums with poorly sealed lids, and lids that were ajar were stored immediately adjacent to an open bulk trash bin. In addition, a gas can, a bed frame, unused equipment, tools, hoses, rags, and litter were observed stored on top of and amongst these in-process food drums.
7. Effective measures must be taken to protect finished food from contamination by raw materials, other ingredients, or refuse, to comply with 21 CFR 110.80(b)(6). However, our inspection found that you are holding and storing raw ingredients, in-process foods, finished product, and food scheduled for rework in unmarked containers. For example, an unmarked container of potassium sorbate preservative was found stored along with other raw ingredients. You must identify and store your raw materials so they are not mistaken or misused whereby they may become contaminants.

Misbranding

1. Your Lime Juice Natural product is misbranded within the meaning of Section 403(a)(1) of the Act [21 U.S.C. § 343(a)(1)] in that the label uses the term "natural" in a manner that is false and misleading. FDA considers use of the term "natural" on a food label to be truthful and non-misleading only when nothing artificial or synthetic has been included in, or has been added to, a food that would not normally be expected to be in the food [58 FR 2302, 2407 (January 6, 1993); 21 CFR 101.22]. The ingredient statement for this product declares the synthetic chemical preservative "sodium benzoate 1%" [sic]. Accordingly, the use of the term "natural" in association with this product is false and misleading.
2. Your Ghara-Ghoroot Lavashak dry brown curd snack product is misbranded within the meaning of section 403(w) of the Act [21 U.S.C. § 343(w)] in that the label fails to declare all the known major food allergens in the manner required by the Act.

Section 201(qq) of the Act [21 U.S.C. 321(qq)] defines as "major food allergens" milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts, and soybeans, as well as any food ingredient that contains protein derived from one of these foods, with the exception of highly refined oils. A food is misbranded under section 403(w) if it is not a raw agricultural commodity and it is, or it contains an ingredient that bears or contains, a major food allergen, unless either:

- The word "Contains," followed by the name of the food source from which the major food allergen is derived, is printed immediately after or is adjacent to the list of ingredients, section 403 (w)(1)(A) of the Act [21 U.S.C. § 343(w)(1)(A)]; or
- The common or usual name of the major food allergen in the list of ingredients is followed in parentheses by the name of the food source from which the major food allergen is derived, except that the name of the food source is not required when either the common or usual name of the ingredient uses the name of the food source from which the major food allergen is derived; or the name of the food source from which the major food allergen is derived appears elsewhere in the ingredient list (unless the name of the food source that appears elsewhere in the ingredient list appears as part of the name of a food ingredient that is not a major food allergen), section 403 (w)(1)(B) of the Act [21 U.S.C. § 343(w)(1)(B)].

The ingredient statement for the Ghara-Ghoroot Lavashak declares both "Whey" and "Yogurt" as ingredients. However, the product label fails to declare the presence of the major food allergen, milk. Furthermore, as is discussed below, you are required to declare the component ingredients of the yogurt.

3. Your Sour Cherry Juice (two unique brand names) and Sour Grape Juice (four unique brand names) products are misbranded within the meaning of section 403(i)(1) of the Act [21 U.S.C. § 343(i)(1)] because the statement of identity does not bear an accurate common or usual name. According to 21 CFR 102.33(a), for a carbonated or noncarbonated beverage that contains less than 100 percent and more than 0 percent fruit or vegetable juice, the common or usual name shall be a descriptive name that meets the requirements of 21 CFR 102.5(a) and, if the common or usual name uses the word "juice," shall include a qualifying term such as "beverage," "cocktail," or "drink" appropriate to advise the consumer that the product is less than 100 percent juice (e.g., "diluted apple juice beverage" or "apple juice drink"). Your products are labeled as "juice", however based on your list of ingredients for each juice, your products do not qualify to be labeled as "juice" without a qualifying term to indicate that the product contains less than 100 percent juice.
4. Your juice products are further misbranded within the meaning of section 403(i)(2) of the Act [21 U.S.C. § 343(i)(2)]. In particular,
 - Your Sour Cherry Juice (two unique brand names) and Sour Grape Juice (four unique brand names) products do not contain declarations of the percentage of juice in the products as required by 21 CFR 101.30(b).
 - Your Sour Grape Juice products (four unique brand names) are fabricated from two or more ingredients and the labels fail to declare the common or usual name of each ingredient in accordance with section 403(i)(2) of the act. Your formulation sheet for these four Sour Grape Juice products indicates that water, salt, and citric acid are used; however the ingredients are not declared on your label.
 - Your Vegetable Stew ingredient statement fails to include onion, water, garlic powder, turmeric, black pepper, citric acid, salt, and sodium benzoate (and a separate description of its function, as required by 21 CFR 101.22(j) in situations where a chemical preservative is added), all of which are contained in the product according to your production records. For foods that are fabricated from two or more ingredients, the common or usual name of each such ingredient must appear on the label as required by section 403(i)(2) of the act and in the manner set forth in 21 CFR 101.4. Furthermore, the label lists the ingredient mint, which is not in the product recipe. Under section 403(a)(1) of the Act [21 U.S.C. § 343(a)(1)], a food is misbranded if its labeling is false in any particular.
 - Your Ghara-Ghoroot Lavashak product label declares "Yogurt" as an ingredient, but it does not comply with 21 CFR 101.4(b)(2), which sets out two alternatives for designating an ingredient such as yogurt that itself contains two or more ingredients. In such a situation, you must either declare the established common or usual name of the ingredient (here, "yogurt") followed by a parenthetical listing of all ingredients

contained therein in descending order of predominance (unless the ingredient is a food subject to a definition and standard of identity that has specific labeling provisions for optional ingredients) [21 CFR 101.4(b)(2)(i)]; or else you must incorporate into the statement of ingredients in descending order of predominance in the finished food, the common or usual name of every component of the ingredient without listing the ingredient itself [21 CFR 101.4(b)(2)(ii)]. While yogurt is subject to a definition and standard of identity, the relevant provision states that each of the ingredients used in yogurt shall be declared on the label as required by the applicable sections of part 101 [21 CFR 131.200(g)].

5. Your products are misbranded within the meaning of Section 403(q) of the Act [21 U.S.C. § 343(q)] in that the nutrition facts information is not in an appropriate format as defined in 21 CFR 101.9. Specifically,

- The sodium content for your Shemshad Sour Grape Juice and Shams Sour Grape Juice products is not expressed to the nearest 5-milligram increment, as required when a serving contains 5 to 140 milligrams of sodium [21 CFR § 101.9(c)(4)];
- Because the saturated fat for your Lavashak Alou contains less than 0.5 gram per serving, the content must be expressed as zero [21 CFR § 101.9(c)(2)(i)];
- The saturated fat declaration for your Lavashak Alou must be listed above the trans fat declaration in accordance with 21 CFR § 101.9(c);
- The heading "Amount Per Serving" in the Nutrition Facts box for your Indo-European Sour Grape Juice is not provided, as required by 21 CFR 101.9(d)(1)(iv);
- The serving size declared for your Walnut Stew is inaccurate and must be determined based on the reference amount customarily consumed (RACC) [21 CFR 101.12(b)]. Specifically, your Walnut Stew declares a serving size of ½ cup (58g), however 21 CFR 101.12(b), Table 2 for Soup (all varieties) indicates that the serving size for soup must be based on the RACC of 245g;
- The quantity of trans fat is not provided for in your Walnut Stew and Ghara-Ghoroot Lavashak, as required by 21 CFR 101.9(c)(2)(ii) for products that contain 0.5 grams or more of total fat in a serving. Your Walnut Stew declares 4 grams of total fat per serving (see above for a discussion of your inaccurate serving size for this product), and your Ghara-Ghoroot Lavashak declares 5 grams of total fat per serving;
- Calcium in your GOLCHIN Sour Grape Juice is not expressed to the nearest 2-percent increment, as required by 21 CFR 101.9(c)(8)(iii) for products containing up to and including 10 percent of the Daily Value (DV);
- Iron and Vitamin C in your GOLCHIN Sour Grape Juice are not expressed to the nearest 5-percent increment, as required by 21 CFR 101.9(c)(8)(iii) for products containing above 10 percent and up to and including 50 percent of the DV;
- The amount of protein is not provided for in your GOLCHIN Sour Grape Juice, as required by 21 CFR 101.9(c)(7);

For additional information on General Food Labeling requirements go to

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/default.htm>².

6. Your Shemshad Ghara-Ghoroot Lavashak, Shemshad Sour Grape Juice and Shams Sour Grape Juice products are misbranded with the meaning of section 403(f) of the Act [21 U.S.C. § 343(f)], because your product labels contain information in two languages but do not repeat all the required label information in both languages. In accordance with 21 CFR 101.15(c)(2), if a product label contains any representation in a foreign language, all words, statements, and other information required by or under authority of the Act to appear on the label must appear in the foreign language.

Unapproved New Drug

Your GOLCHIN Sour Grape Juice product label promotes your juice beverage product for a condition that causes it to be a drug under section 201(g)(1) of the Act [21 U.S.C. § 321(g)(1)]. This product label contains the therapeutic claim "Helps lower high cholesterol," which establishes that the product is a drug because it is intended for use in the cure, mitigation, treatment, or prevention of disease.

The marketing of this product with this claim violates the Act. Your product is not generally recognized as safe and effective for the above-referenced use. Therefore, the product is a "new drug" under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

The above violations are not intended to be an all-inclusive list of violations in your plant. It is your responsibility to ensure that your facility and all of your products are in compliance with the Act and all applicable federal regulations.

You should take prompt action to correct the violations cited in this letter and to establish and implement procedures that will prevent them from occurring in the future. Failure to implement lasting corrective action on violations may result in regulatory action being initiated by FDA without further notice, such as seizure, injunction, and/or issuance of an Order of Need to Obtain and Hold a Temporary Emergency Permit.

We have reviewed your response dated October 15, 2010, to the FDA Form 483 issued during the September 2010 inspection. Your response is inadequate because although it indicates that corrections have or will be made regarding several of the violative conditions documented on the Form 483, it does not provide any documentation or other evidence of actions your firm has taken to correct the violations noted. Examples of such evidence include: evidence that you are working with a process authority or that your scheduled processes have been filed with the FDA; processing and production records; documentation of any pest-control measures you have taken; documentation of measures you have taken to institute hygienic practices; and revised product labels.

In addition to the above violations, we also have the following labeling comments:

- Your Sour Grape Juice product labels (four unique brand names) declare the percent of Daily Value for Calcium differently from one another, although the products are manufactured in an identical manner. The Shams Sour Grape Juice and Shemshad Sour Grape Juice products state that they contain 48% of the DV for Calcium, whereas your GOLCHIN Sour Grape Juice product states that it contains 1% of the DV for Calcium. We question the accuracy of these declarations as well as the source of Calcium you account for in your juice products. Your formulation sheet for the four Sour Grape Juice products indicates that sour grape juice, water, salt, and citric acid are the only ingredients used in the products' manufacture. Your fourth brand of Sour Grape Juice products, the Indo-European Sour Grape Juice, has a place on its label where the percent of DV for Calcium is indicated, but there is no percentage listed; there is only the symbol "%". The symbol "%" is not defined, nor is a value for Calcium presented anywhere on the label [21 CFR 101.9(c)(8)].
- Your Ghara-Ghoroot Lavashak product label declares "Approx. 2 Oz (56.7g)" for the net quantity of contents statement. The net quantity statement should accurately reveal the quantity of food in the package in accordance with 21 CFR 101.105(g).
- If the citric acid is functioning as a preservative in your finished juice products, that function needs to be included in accordance with the requirements of section 403(k) of the Act [21 U.S.C. § 343(k)] and 21 CFR 101.22(j).

We request that you notify this office in writing within 15 working days from your receipt of this letter of the current status of your corrective actions and the specific steps you have taken to correct the noted violations. In your response, include documentation of your corrective actions or steps towards long term, corrective action. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and please include a timetable for the implementation of any remaining corrections.

Please send your reply to the Food and Drug Administration, Attention:

Blake Bevill
Director Compliance Branch
Los Angeles District
19701 Fairchild
Irvine, CA, 92612-2506

If you have questions regarding any issues in this letter, please contact David Whitman, Compliance Officer at 858-550-3850 x106.

Sincerely,

/s/

Alonza E. Cruse
District Director
Los Angeles District

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U.S. Department of Health & Human Services

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